

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D0524399	(X3) Date Survey Completed 08/15/2023
Name of Provider or Supplier West Valley Dermatology	Street Address, City, State 4133 Pioneer Parkway Suite 120, West Valley City, UT	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the office manager, the laboratory failed to follow the laboratory's procedure to monitor and record room temperature and humidity. The laboratory performs approximately 326 histopathology tests annually. Findings include: 1. During laboratory record review, the laboratory failed to produce records of temperature and humidity readings. 2. Interview with office manager on 8/15/2023 at 1:27 PM, confirmed the laboratory did not monitor or record the laboratory temperature or humidity since the last survey on 1/23/2021. 3. Review of 'Quality Control Program' procedure revealed the laboratory staff failed to follow their procedure as stated: 'Temperatures will be taken by an employee in the laboratory and recorded'.</p>
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a</p>

maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on record review and interview with the Laboratory Director, the laboratory failed to perform preventative maintenance for one of one microscopes since the last survey on 1/23/2021. Findings include: 1. Record review of the microscope maintenance records revealed lack of microscope maintenance documentation since the last survey performed on 1/23/2021. 2. Interview with the Laboratory Director on 8/15/2023 at 1:35 PM, confirmed that the laboratory failed to perform preventative maintenance on one of one microscopes since the last survey on 1/23/2021.